Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01/04/2011 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating some health problems by using an anandamide or one of its precursors, does not reasonably provide enablement for the prevention of theses health problems. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of

the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

1) The breadth of claims: claim 15 is directed to a method of making a composition for preventing an anandamide mediated ailment selected from the group consisting of hypertension, glaucoma, insomnia, pain, inflammation, migraine headaches, loss of appetite, nausea, cramps, etc.

2) The nature of the invention: The invention is drawn to a composition for oral administration comprising a naturally occurring precursor that is a compound having anandamide activity for use as a medicament. The rejected claim, however, is drawn to a method of making a dosage form effective in preventing an anandamide-mediated ailment selected from the group consisting of hypertension, glaucoma, etc.

3) The state of the prior art: The state of the art is very high in terms of compositions comprising anandamide and/or precursors containing compound for the treatment of for example, psychiatric problems, pain, migraine headaches, inflammation, glaucoma, hypertension, and vocalization problems. Although a number of publications describe methods of treating different ailments using compounds comprising anandamides (US 5, 618, 955, US 20040127518, cited previously), there is no evidence in the prior art that the instant composition would entirely prevent all or any of the listed ailments.

4) The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention prevents all the listed health problems. The prevention of all these ailments is considered a very broad claim. With respect to the methods recited in the instant application, there is a substantial gap between treatment and prevention. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

5) Predictability of the art: The prior does not teach a method of preventing hypertension, glaucoma, insomnia, pain, inflammation, migraine headaches, loss of appetite, nausea, cramps, diarrhea, gut upsets, intestinal motility disturbances, asthma, nervousness, aggressive behavior, excessive timidity, inability to sleep, catalepsy, low mood, depression, spasms, poor motor control, tics, excessive stress, spasticity, multiple sclerosis, and vocalization, poor language acquisition, skin inflammation, and excess nociception.

6) The presence or absence of working examples: Applicant describes no examples in the instant specification, none of which teach a method of preventing of any ailment. Overall, applicant fails to provide examples indicating that the instant composition can prevent the health problems listed in claim 15 by an oral composition comprising anandamides. Therefore, the practitioner would turn to trial and error experimentation to make/use of the instant compositions for preventing health problems, without guidance from the specification or the prior art.

7) The quantity of experimentation: In the instant case, there is a substantial gap between treatment and prevention. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the composition as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing a system for preventing health problems recited in claim 15 by an oral composition comprising anandamide. The factors are not sufficiently discussed in the specification to provide guidance to utilize the invention as claimed.

8) The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 depends upon a cancelled claim. The examiner for the purposes of compact prosecution will treat the claim as though it depends upon claim 1, however correction is required.

With regards to claim 19 it is unclear if the naturally occurring precursor is "synthesized" with another material or if applicants intend

to mean that the precursor is synthesized from some starting materials not described in the claim. Clarification is required.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-4,6,9-11,13-16,18-19 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Crissinger et al. (US 5,411,751), as evidenced by Bennett et al. ("SUPPRESSION OF RENAL INFLAMMATION WITH VITAMINS A AND E IN ASCENDING PYELONEPHRITIS IN RAT", The Journal of Urology, Volume 161, Issue 5, May 1999, Pages 1681-1684).

Crissinger teaches use of nutritional products for treating or preventing damage to the intestinal epithelium of infants such as in necrotizing enterocolitis, a condition considered to read on inflammation, gut upsets and pain as recited in claim 16. See abstract, col 1 lines 13-33 and claims. The nutritional product contained a mixture of fatty acid esters including ethyl arachidonate and other esters of arachidonic acid (meeting the claimed precursor for a compound with anandamide activity) and ethyl palmitate and other esters of palmitic acid (meeting the claimed inhibitor of anandamide). See claims. The composition

could also contain triglycerides containing any of the named fatty acids in combination such as arachidonic acid, palmitic, linolenic etc. See col 1 line 60-cool 2 line 36, col 4 lines 57-64. The composition additionally contained one or more components including vitamins such as vitamin A and E, which have anti-inflammatory properties as evidenced by Bennett (See entire disclosure of Bennett especially conclusion). See claim 1 and col 3 lines 31-68. Regarding the claimed properties of the precursor said to metabolize to a compound with anandamide activity and the claimed inhibitor of an anandamide inactivating enzyme, since the compounds of Crissinger are the same as the claimed precursors and inhibitors (arachidonate and palmitate respectfully) it is inherent that the same compound will feature the same biological activities. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). MPEP 2112.01 [R-3] II.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Marzo V. 2-Arachidonoyl-glycerol as an "endocannabinoid": limelight for a formerly neglected metabolite, Biochemistry (Mosc). 1998 Jan;63(1):13-21 in view of Burch et al. US 6552031, for the reasons set forth in the previous office action filed 06/04/2009.

Regarding the new limitation within independent claims 1,14-16 which require an inhibitor such as palmitate, oleate etc., Marzo teaches that 2-AG in combination with 2-monopalmitoyl-glycerol caused in 8 fold potentiation of 2-AG binding to CB2 receptors, thus rendering a higher affinity for the metabolite.

Claim 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Marzo V. 2-Arachidonoyl-glycerol as an "endocannabinoid": limelight for a formerly

neglected metabolite, Biochemistry (Mosc). 1998 Jan;63(1):13-21 in view of Burch et al. US 6552031 and further in view of Kyle et al WO 94/28913, for the reasons set forth in the previous office action filed 06/04/2009.

Response to Arguments

Applicant's arguments filed 01/04/2011 have been fully considered but they are not persuasive. Applicants assert none of the references used above in the 35 U.S.C. 103(a) rejections teach the claimed inhibitor.

The examiner disagrees, as noted above the primary reference teaches the same claimed inhibitors, palmitate or palmatoylglycerol.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James W Rogers/

Examiner, Art Unit 1618